

CHAPTER 5

STUDY SELECTION AND PARTICIPATION

INTRODUCTION

During the design phase of the Air Force Health Study (AFHS), the authors of the Protocol anticipated that loss to followup would pose the greatest threat to study validity. In particular, they expected differential compliance with relatively more Ranch Hands self-selecting into the study than Comparisons and with health differences of unknown character between refusing Ranch Hands and refusing Comparisons. As a partial correction, the study design specified that refusing Comparisons would be replaced by Comparisons with the same values of the matching variables and the same health perception. In this way, the replacement Comparisons would serve as surrogates for those Comparisons who refused to participate. This would tend to reduce bias due to refusal in the Comparison group and would have the added advantage of maintaining group size. No corresponding strategy for the Ranch Hands was possible since all Ranch Hands had been identified and invited to participate.

The first Comparison in each randomized matched set asked to participate in the Baseline questionnaire and physical examination was identified as the Original Comparison for his respective Ranch Hand (in accordance with the Protocol). If the Original Comparison was noncompliant (i.e., he refused to participate, was partially compliant, or unlocatable), he was replaced by a "replacement" Comparison. Replacement Comparisons were identified in the data base to satisfy the Protocol requirement that they be contrasted with the refusing Original Comparisons (also called refusals). In the case of an unlocatable Original Comparison, this contrast is, of course, not possible. Deceased Original Comparisons were not replaced.

The statistical contrast of replacements and refusals was to be based on responses to a telephone questionnaire administered to refusals and to their potential replacements. This questionnaire assessed self-perception of health, days lost from work due to illness, and medication use, and was to serve as the basis for the health matching required by the Protocol. Although the Protocol was not explicit on this point, it implied that the decision to include or exclude the replacements from the study would be based only on this contrast. A telephone questionnaire was administered to refusals at Baseline and 1985 followup examinations. At the 1987 followup examination, refusals were simply asked during the scheduling process for their self-perception of health. Health-matching replacements was not implemented at Baseline but was implemented at the 1985 and 1987 followup examinations. Replacement Comparisons were matched to noncompliant (refusal, partially compliant, or unlocatable) Original Comparisons with respect to age, race, rank, and occupation at all examinations.

In this chapter, the cumulative study compliance is summarized and refusing Ranch Hands and Comparisons at the 1987 followup examination are contrasted with respect to reason for refusal and reported health status. All Ranch Hands and Comparisons were contrasted on reported health with adjustment for compliance (fully compliant, refusal). Scheduling patterns were compared by plotting cumulative compliance versus calendar time for Ranch Hands, Original Comparisons, and replacement Comparisons.

Adherence to the replacement algorithm for noncompliant Original Comparisons was investigated at the 1987 followup. Replacement Comparisons were contrasted with the Original Comparisons they replaced on reported health status. Ranch Hands and Comparisons at least partially compliant in the 1987 followup were descriptively contrasted on reported health, medication, and work loss, with adjustment for compliance status (full, partial); these data were too sparse for formal statistical analysis. Finally, Ranch Hands and Comparisons who passively refused the 1987 followup examination were contrasted with respect to reported health status.

FACTORS KNOWN OR SUSPECTED TO INFLUENCE STUDY PARTICIPATION

A multitude of factors influence self-selection. These may be broadly classified as health, logistic, operational, publicity, or demographic factors. For example, health factors are thought to include self-perception of health as well as demonstrable health indicators, such as medication use and work days lost due to illness or injury. Logistic factors include distance to the examination site, reluctance to spend time away from family or job, income, and occupation. Demographic factors include flying status, age, race, or military duty status (active, retired, separated). Operational factors include any aspect of study operation that may cause differential compliance, such as differential treatment of participants during scheduling, physical examination, interview, or debriefing procedures. Publicity factors are related to national attitudes and media presentations regarding the Agent Orange issue, the Vietnam war, veteran health care, or health care in general. Additionally, these considerations may affect people differently and, in particular, may influence Ranch Hands differently than Comparisons.

The decision to volunteer for this study or any study is admittedly complex, making statistical assessment of compliance bias difficult and necessarily crude in that many of the factors contributing to self-selection cannot be measured directly. Instead, compliance bias was investigated at the 1987 followup as in the 1985 followup and Baseline reports, with respect to self-perception of health, medication use, and days lost from work due to illness or injury.

1987 FOLLOWUP SCHEDULING AND REPLACEMENT OPERATION

Matching replacements to noncompliant Original Comparisons on the basis of reported health status, as well as the four matching variables (age, race, rank, and occupation), was continued at the 1987 followup scheduling operation. The telephone survey data base collected at the 1985 followup was utilized to obtain self-perception of health of refusals and all potential replacement candidates who had not been previously contacted. If the replacement or refusal was not represented in the telephone survey data, he was asked at scheduling for his health status. Examination group integrity was encouraged at the 1987 followup as during the 1985 followup (the 81 groups were randomly scheduled for an examination). However, study participants were given the option to remain with their group or to reschedule their examination at a more convenient time.

1987 FOLLOWUP COMPLIANCE

Eighty-four percent (995/1,188) of the eligible Ranch Hands and 77 percent (939/1,224) of the eligible Original Comparisons participated in the 1987 followup examination and questionnaire process. Of 494 replacement Comparisons invited for the 1987 followup, 360 (73%) chose to attend the examination. These and other counts are summarized in Tables 5-1 through 5-4. Table 5-1 provides counts for the Ranch Hands. Total Comparison group counts are shown in Table 5-2. Original Comparison counts are summarized in Table 5-3 and replacement Comparison counts are provided in Table 5-4. Undefined categories are indicated by dashes. For example, a partially compliant participant at Baseline (completed the Baseline questionnaire) could not be partially compliant at a later examination, since partial compliance only occurred when a participant agreed to the Baseline questionnaire but refused to attend the physical examination. Ninety-two percent of living Ranch Hands and 93 percent of living Comparisons who were fully compliant at the Baseline examination returned for the 1987 followup examination.

Fourteen Ranch Hands, 17 Original Comparisons, and 42 replacement Comparisons were examined for the first time at the 1987 followup examination. Table 5-5 describes these newly examined participants in terms of their compliance at the Baseline and 1985 followup studies. Nine of the 14 newly examined Ranch Hands were partially compliant at a previous study, and 2 refused both previous examinations. Three Ranch Hands were new to the study between the 1985 and 1987 followup.

Eleven Original Comparisons were partially compliant at a previous study, and two were new to the study between the 1985 and 1987 followups. Four Originals were refusals at previous studies. Eight (4+2+2) replacement Comparisons were partially compliant at Baseline or the 1985 followup, and 12 (9+3) had previously refused (Table 5-5). Twenty-eight replacements were new to the study between the two followups (Table 5-4). Twenty-two of these 28 replacements were newly examined at the 1987 followup (Table 5-5). Six of these 28 were partially compliant at the 1987 followup.

REFUSING RANCH HANDS VERSUS REFUSING COMPARISONS

Of the 1,188 Ranch Hands and 1,731 Comparisons eligible for the 1987 followup examination, 171 Ranch Hands and 360 Comparisons chose not to attend. Their reasons for refusal are summarized in Table 5-6.

A test of association between reason for refusal and group adjusted for age and rank was performed; the results are summarized in Table 5-7. Due to sparse data, reason for refusal was collapsed to three categories: logistic (job commitment, no time or interest, travel distance--family, confidentiality, financial hardship); passive (passive refusal); and other (fear of physical, dissatisfaction with the U.S. Air Force [USAF], health reasons, dissatisfaction with Baseline, other). The covariates age and rank were dichotomized for the analysis (born before 1942 and born in or after 1942; officer and enlisted, respectively). Twenty-eight Blacks (8 Ranch Hands and 20 Comparisons) were deleted from this analysis due to small cell counts.

The association between reason for refusal and group adjusted for age and rank was not significant ($p=0.238$). The adjusted association between reason

TABLE 5-1.

**Baseline Compliance and Followup Disposition of Ranch Hands
at the Baseline, 1985, and 1987 Examinations**

Time Period	Disposition	Baseline Compliance					Total
		FC	PC	R	UNL	NS	
Baseline		1,045	129	32	2	0	1,208
Between Baseline and 1985 Followup	New to Study	--	--	--	--	9	9
	Died	10	9	0	0	0	19
1985 Followup	Eligible for 1985 Followup	1,035	120	32	2	9	1,198
	Contact Not Attempted	0	0	0	0	0	0
	Contact Attempted	1,035	120	32	2	9	1,198
	Subject Unlocatable	28	12	0	0	0	40
	Subject Refused	36	69	29	1	0	135
	Subject Partial Compliant	--	--	3	0	4	7
	Subject Fully Compliant	971	39	0	1	5	1,016
Between 1985 and 1987 Followup	New to Study	--	--	--	--	4	4
	Died	11	3	0	0	0	14
1987 Followup	Eligible for 1987 Followup	1,024	117	32	2	13	1,188
	Contact Not Attempted	0	0	0	0	0	0
	Contact Attempted	1,024	117	32	2	13	1,188
	Subject Unlocatable	9	10	2	0	0	21
	Subject Refused	71	70	26	1	3	171
	Subject Partial Compliant	--	--	1	0	0	1
	Subject Fully Compliant	944	37	3	1	10	995

Legend: FC = Fully Compliant at Baseline
 PC = Partially Compliant at Baseline
 R = Refusal at Baseline
 UNL = Unlocatable at Baseline
 NS = New to Study Since Baseline

TABLE 5-2.

**Baseline Compliance and Followup Disposition of Comparisons
at the Baseline, 1985, and 1987 Examinations**

Time Period	Disposition	Baseline Compliance					Total
		FC	PC	R	UNL	NS	
Baseline		1,224	307	128	9	0	1,668*
Between Baseline and 1985 Followup	New to Study	--	--	--	--	73	73**
	Died	16	9	1	0	0	26
1985 Followup	Eligible for 1985 Followup	1,208	298	127	9	73	1,715
	Contact Not Attempted	0	0	0	0	0	0
	Contact Attempted	1,208	298	127	9	73	1,715
	Subject Unlocatable	39	27	0	0	1	67
	Subject Refused	30	175	87	5	30	327
	Subject Partial Compliant	--	--	22	0	6	28
	Subject Fully Compliant	1,139	96	18	4	36	1,293
Between 1985 and 1987 Followup	New to Study	--	--	--	--	32	32
	Died	14	1	1	0	0	16
1987 Followup	Eligible for 1987 Followup	1,194	297	126	9	105	1,731
	Contact Not Attempted	0	0	0	0	2	2
	Contact Attempted	1,194	297	126	9	103	1,729
	Subject Unlocatable	8	21	8	3	3	43
	Subject Refused	73	180	87	3	17	360
	Subject Partial Compliant	--	--	13	0	14	27
	Subject Fully Compliant	1,113	96	18	3	69	1,299

*The Baseline Report total count of 1,669 listed in the Baseline Report should be 1,668 due to the inclusion of 1 ineligible Comparison.

**Twenty-one of these 73 were actually identified as eligible for the study during Baseline but the contract ended before they could be located by the contractor.

Legend: FC = Fully Compliant at Baseline
 PC = Partially Compliant at Baseline
 R = Refusal at Baseline
 UNL = Unlocatable at Baseline
 NS = New to Study Since Baseline

TABLE 5-3.

**Baseline Compliance and Followup Disposition of Original Comparisons
at the Baseline, 1985 and 1987 Examinations**

Time Period	Disposition	Baseline Compliance					Total
		FC	PC	R	UNL	NS	
Baseline		936	220	78	3	--	1,237
Between Baseline and 1985 Followup	New to Study	--	--	--	--	17	17
	Died	11	9	1	0	0	21
1985 Followup	Eligible for 1985 Followup	925	211	77	3	17	1,233
	Contact Not Attempted	0	0	0	0	0	0
	Contact Attempted	925	211	77	3	17	1,233
	Subject Unlocatable	29	20	0	0	1	50
	Subject Refused	24	129	61	2	4	220
	Subject Partial Compliant	--	--	7	0	1	8
	Subject Fully Compliant	872	62	9	1	11	955
Between 1985 and 1987 Followup	New to Study	--	--	--	--	4	4
	Died	12	1	0	0	0	13
1987 Followup	Eligible for 1987 Followup	913	210	77	3	21	1,224
	Contact Not Attempted	0	0	0	0	0	0
	Contact Attempted	913	210	77	3	21	1,224
	Subject Unlocatable	7	14	8	2	1	32
	Subject Refused	51	132	52	1	6	242
	Subject Partial Compliant	--	--	11	0	0	11
	Subject Fully Compliant	855	64	6	0	14	939

Legend: FC = Fully Compliant at Baseline
 PC = Partially Compliant at Baseline
 R = Refusal at Baseline
 UNL = Unlocatable at Baseline
 NS = New to Study Since Baseline

TABLE 5-4.

**Baseline Compliance and Followup Disposition of Replacement Comparisons
at the Baseline, 1985, and 1987 Examination**

Time Period	Disposition	Baseline Compliance					Total
		FC	PC	R	UNL	NS	
Baseline		288	87	50	6	--	431
Between Baseline and 1985 Followup	New to Study	--	--	--	--	56	56
	Died	5	0	0	0	0	5
1985 Followup	Eligible for 1985 Followup	283	87	50	6	56	482
	Contact Not Attempted	0	0	0	0	0	0
	Contact Attempted	283	87	50	6	56	482
	Subject Unlocatable	10	7	0	0	0	17
	Subject Refused	6	46	26	3	26	107
	Subject Partial Compliant	--	--	15	0	5	20
	Subject Fully Compliant	267	34	9	3	25	338
Between 1985 and 1987 Followup	New to Study	--	--	--	--	28	28
	Died	2	0	1	0	0	3
1987 Followup	Eligible for 1987 Followup	281	87	49	6	84	507
	Contact Not Attempted	0	0	0	0	2	2*
	Contact Attempted	281	87	49	6	82	505
	Subject Unlocatable	1	7	0	1	2	11
	Subject Refused	22	48	35	2	11	118
	Subject Partial Compliant	--	--	2	0	14	16
	Subject Fully Compliant	258	32	12	3	55	360

*Records indicate that the contractor failed to recognize these two individuals and consequently did not attempt to schedule them.

Legend: FC = Fully Compliant at Baseline
 PC = Partially Compliant at Baseline
 R = Refusal at Baseline
 UNL = Unlocatable at Baseline
 NS = New to Study Since Baseline

TABLE 5-5.

**New Fully Compliant Participants at the 1987 Followup by
Group and Previous Compliance**

Previous Compliance		Group		
Baseline	1985 Followup	Ranch Hand	Original Comparison	Replacement Comparison
Partially Compliant	Refusal	5	9	4
	Unlocatable	1	2	0
Refusal	Partially Compliant	1	0	2
	Refusal	2	2	3
New to Study	Partially Compliant	2	0	2
	Refusal	0	2	9
	New to Study	3	2	22
Total		14	17	42

for refusal and age was of borderline significance ($p=0.063$); a greater percentage of men born in or after 1942 were passive refusals (26%) than men born before 1942 (18%). There were no significant higher order interactions.

Of the 531 refusals, reported health status was available on 150 (88%) of 171 refusing Ranch Hands and 324 (90%) of 360 refusing Comparisons. Data sources included AFHS questionnaires at the 1985 followup and at Baseline, the telephone survey at the 1985 followup, and the noncompliant telephone questionnaire administered at Baseline. Their responses are presented in Table 5-8. Among the 474 refusals responding to the health status question, there was a borderline significant association between group (Ranch Hand, Comparison) and reported health ($p=0.080$); a greater percentage of refusing Comparisons (47%) reported excellent health than refusing Ranch Hands (40%), and a greater percentage of refusing Ranch Hands (11%) reported fair health than Comparisons (5%).

At the 1985 followup, the reported health status of 35 refusing Ranch Hands was not associated with that of 42 refusing Comparisons ($p=0.720$). The large difference in significance levels between these two analyses appears due to a much larger sample size at the 1987 followup. In addition, the direction and magnitude of the difference between the groups in the good and fair categories changed between the 1985 and 1987 followups.

Ideally, compliance bias between the groups should be assessed by comparing the health of refusing and fully compliant participants with adjustment for the matching variables. The only data available on the refusing participants, however, are their responses to the health status question at the 1987

TABLE 5-6.
Reason for Refusal by Group*

Reason	Group			
	Ranch Hand		Comparison	
	Number	Percent	Number	Percent
Fear of Physical	1	0.6	4	1.1
Job Commitment	32	18.7	61	17.0
Dissatisfaction with USAF	10	5.8	11	3.1
No Time or Interest	28	16.4	79	22.1
Travel Distance, Family	5	2.9	17	4.7
Confidentiality	1	0.6	4	1.1
Health Reasons	11	6.4	16	4.5
Passive Refusal	40	23.4	78	21.8
Dissatisfaction With Baseline	0	0.0	1	0.3
Financial Hardship	1	0.6	1	0.3
Other (unspecified)	42	24.6	86	24.0
Total	171		358	

*Data on two Comparisons were missing.

followup and previous studies. A test of association between reported health status and group adjusted for compliance, age, and rank was performed. The results are summarized in Table 5-9. Due to sparse data, reported health status was collapsed to two categories: excellent/good and fair/poor. The covariates age and rank were dichotomized (born before 1942 and born in or after 1942; officer and enlisted, respectively). The covariate occupation (flying or ground duty) could not be accommodated. Blacks (n=166) were excluded from the analysis due to small cell counts.

The association between reported health status and group adjusted for compliance, age, and rank was not significant ($p=0.310$). The adjusted association between reported health status and compliance was statistically significant ($p<0.001$) for both groups combined. As can be seen in the

TABLE 5-7.

Reason for Refusal Versus Group Adjusted
for Age and Rank Among Nonblacks

Age	Rank	Group	Reason for Refusal						Total
			Logistic		Passive		Other		
			Number	Percent	Number	Percent	Number	Percent	
<1942	Officer	RH	17	42.5	7	17.5	16	40.0	40
		Comp	36	45.6	13	16.4	30	38.0	79
	Enlisted	RH	18	36.7	9	18.4	22	44.9	49
		Comp	30	44.1	14	20.6	24	35.3	68
<1942	Officer	RH	8	42.1	7	36.8	4	21.1	19
		Comp	24	33.3	19	26.4	29	40.3	72
	Enlisted	RH	20	36.4	15	27.3	20	36.4	55
		Comp	66	55.5	27	22.7	26	21.8	119

Abbreviations: RH = Ranch Hand
Comp = Comparison

TABLE 5-8.

Reported Health Status of Refusals at the 1987 Followup

Reported Health Status	Group			
	Ranch Hand		Comparison	
	Number	Percent	Number	Percent
Excellent	60	40.0	153	47.2
Good	65	43.3	143	44.1
Fair	16	10.7	17	5.2
Poor	9	6.0	11	3.4
Total	150		324	

TABLE 5-9.

**Reported Health Status Versus Group Adjusted
for Compliance, Age, and Rank Among Nonblacks**

Compliance	Birth Year	Rank	Group	Reported Health Status				Total
				Excellent/Good		Fair/Poor		
				Number	Percent	Number	Percent	
Fully Compliant	<1942	Officer	RH	281	94.6	16	5.4	297
			Comp	359	95.7	16	4.3	375
		Enlisted	RH	238	89.5	28	10.5	266
			Comp	299	89.0	37	11.0	336
	≥1942	Officer	RH	73	97.3	2	2.7	75
			Comp	110	98.2	2	1.8	112
		Enlisted	RH	282	94.3	17	5.7	299
			Comp	369	93.4	26	6.6	395
Refusal	<1942	Officer	RH	31	88.6	4	11.4	35
			Comp	63	94.0	4	6.0	67
		Enlisted	RH	37	80.4	9	19.6	46
			Comp	54	81.8	12	18.2	66
	≥1942	Officer	RH	14	87.5	2	12.5	16
			Comp	64	98.5	1	1.5	65
		Enlisted	RH	38	80.9	9	19.1	47
			Comp	101	91.0	10	9.0	111

Abbreviations: RH = Ranch Hand
Comp = Comparison

percentages in Table 5-9, refusing participants report poorer health more often than their fully compliant counterparts, except for officer Comparisons born in or after 1942. It is of interest that, among refusals, Ranch Hands consistently reported poorer health more often than Comparisons. The interaction of reported health status, group, and compliance was borderline significant ($p=0.084$).

SCHEDULING AT 1985 AND 1987 FOLLOWUP

During the 1985 followup scheduling period, the schedulers were required to find and schedule a willing health-matched replacement within 5 working days of a confirmed refusal to correct differences in the pattern of group scheduling experienced at Baseline. This constraint proved impractical to implement since Comparisons would often vacillate, forcing a series of repeated telephone calls. Rather than terminate the process at 5 days, as required by the contract, the Air Force directed the schedulers to continue their recruiting attempts, sometimes for several months. Hence, new health-matched replacements were brought into the study much later than other participants. At the 1987 followup, the Air Force required that schedulers attempt to schedule health-matched replacements within 15 working days of identifying a refusal.

At the 1987 followup, the 15-day scheduling constraint also proved impractical due to the Comparisons' hesitancy to schedule. The Air Force directed schedulers to extend their recruiting attempts in an effort to provide maximum opportunity for Comparisons to participate. The percent completing the physical examination by calendar date is plotted in Figure 5-1 for Ranch Hands, Original Comparisons, replacement Comparisons, and all Comparisons. These patterns are similar to those seen at 1985 followup. Cumulative participation by month for all three examinations is shown in Appendix C.

REPLACEMENT COMPARISONS VERSUS THE NONCOMPLIANT ORIGINAL COMPARISONS THEY REPLACED

A contrast of refusing Original Comparisons and their replacements based on reported health status was not accomplished at Baseline since the necessary data were not available at the time. At the 1985 followup, a short noncompliance questionnaire similar to the telephone survey questionnaire was used to elicit reported health status of refusing Comparisons.

Of 288 Comparisons replaced at Baseline, only 57 responded to the short noncompliance telephone questionnaire. These 57 comprised 38 Original Comparisons and 19 replacements. Replacements were statistically contrasted with the refusing Comparisons they replaced based on their reported health status. This contrast was summarized in Table 5-9 of the 1985 followup report. There was no statistical difference in reported health patterns between refusing Original Comparisons and their replacements. It is noteworthy that 53 percent of Original refusing Comparisons were matched, by chance, perfectly to their replacements, on reported health status.

In April 1985, all previously uncontacted living Comparisons were identified for telephone contact to assess their current health. This health status information was necessary for matching replacements to refusing Original Comparisons. From 9,982 available Comparisons, 7,963 (80%) were identified for the telephone survey. The remaining 2,019 Comparisons included 360 verified as being deceased and 1,659 who had been previously contacted. The group of 1,659 previously contacted Comparisons was comprised of Comparisons who were fully compliant, partially compliant, or refusals at Baseline. Of the 7,963 identified for the telephone survey, responses were obtained from 7,411 Comparisons. These counts correct corresponding figures cited on page 5-7 of the 1985 followup final report.

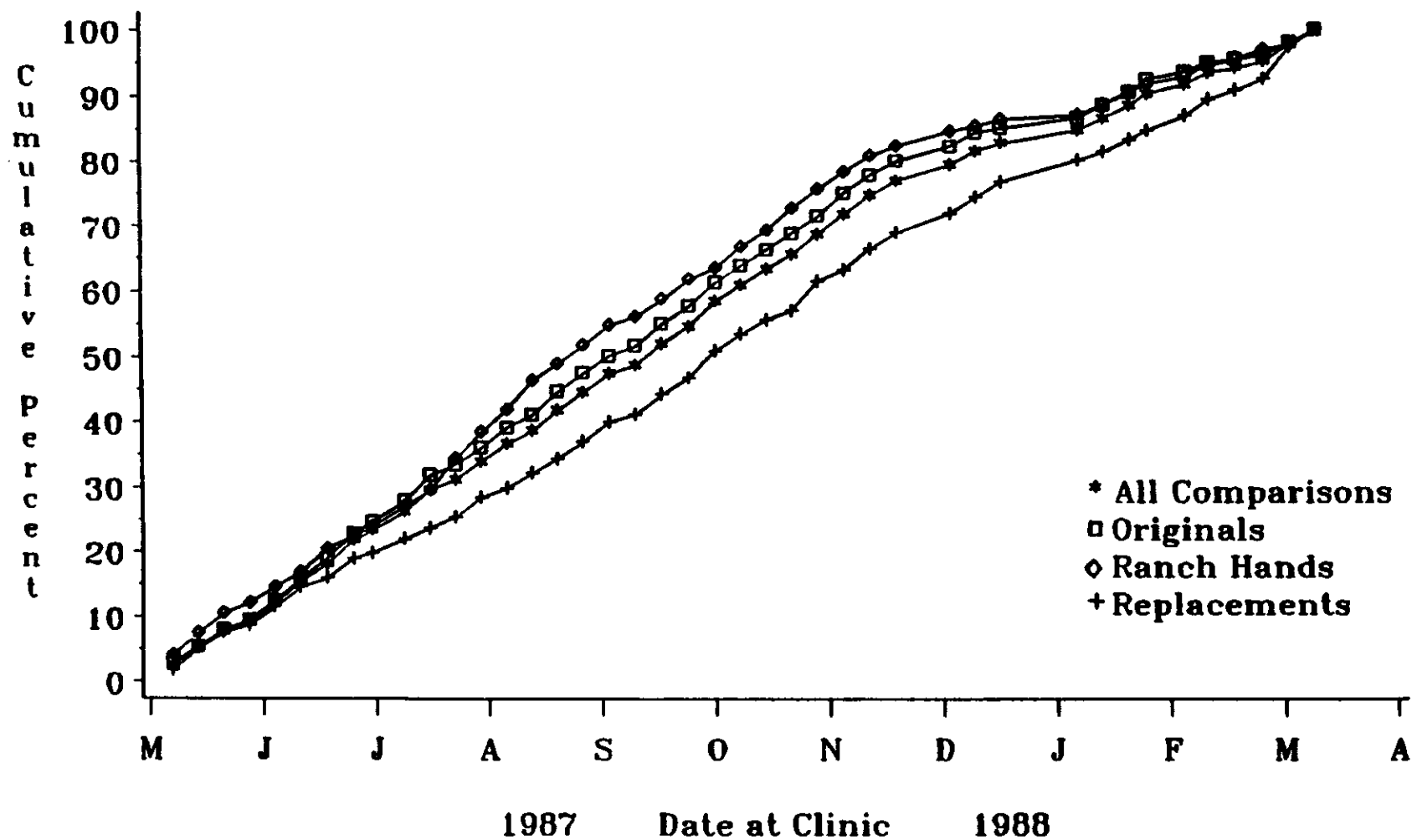


Figure 5-1.
Percent Completed Physical Examination by Calendar Date

The survey questionnaire asked the respondent for his self-perception of health, current prescribed medication use, work days lost due to illness or injury, special health care needs, and income.

As initiated at the 1985 followup, matching replacements to refusing Original Comparisons on the basis of health status as well as age, race, rank, and occupation was maintained at the 1987 followup. The reported health status of new replacements for refusing Original Comparisons was obtained from the telephone survey at the 1985 followup. If a potential replacement was not in the telephone survey data base, he was asked for his self-perception of health during scheduling.

In all, 28 new replacements were added to the study at the 1987 followup. Documentation of replacement actions was located on 24 of these individuals. Of these 24 replacements, only 13 were scheduled to replace refusing Original Comparisons; the remaining 11 mistakenly replaced refusing replacements. Records on health status could be located on 12 of these 13 replacements. Health-matching replacement strategy is summarized on these 12 replacement Comparisons in Table 5-10.

All but one Original reported good or excellent health. The other Original reported fair health. Of the 12 replacements, 1 reported poor health and all others reported good or excellent health. All of the 12 replacements were correctly matched to Originals on health status as required in the Protocol. The inclusion of health-matched replacements corrects possible compliance bias arising from refusal in the Comparison group. The relatively small number of health-matched replacements minimized the actual effect of this bias correction, however.

Two hundred and eighty-five Original Comparisons were noncompliant at the 1987 followup. It is of interest to determine whether these Originals were appropriately replaced at the 1987 followup by compliant replacements. The entire matched set of replacement candidates for each noncompliant Original was reviewed to determine if the appropriate replacement strategy had been followed; a compliant replacement Comparison is present in the Original's matched set. The results on these 285 noncompliant Originals are presented in Table 5-11.

As can be seen from Table 5-11, 230 noncompliant Original Comparisons have been appropriately replaced by compliant replacement Comparisons in their matched set.

There are two circumstances where replacement of noncompliant Original Comparisons has not been accomplished: (1) either the noncompliant Original Comparison belongs to a matched set in which all contacted replacement Comparisons are noncompliant and some Comparisons remain uncontacted, or (2) the noncompliant Original is a member of a matched set in which all replacement Comparisons are uncontacted. These two cases occur 22 and 33 times, respectively.

Health records on these 55 matched sets were reviewed to determine whether replacement action was precluded because of a health mismatch between the refusing Original and all uncontacted replacement Comparisons in the matched set. Health records could not be located on five of the refusing

TABLE 5-10.

**Reported Health Status of Replaced Originals and Their Matched
Replacements at the 1987 Followup**

Replacement's Reported Health	<u>Original Comparison's Reported Health</u>				
	Excellent	Good	Fair	Poor	Total
Excellent	6	0	0	0	6
Good	1	4	0	0	5
Fair	0	0	0	0	0
Poor	0	0	1	0	1
Total	7	4	1	0	12

TABLE 5-11.

Matched Set Compliance of 285 Noncompliant Original Comparisons

Matched Set Compliance	<u>Original's Compliance</u>			
	Refusal	Unlocatable	Partial	Total
At Least One Compliant Replacement	193	26	11	230
All Contacted Replacements Noncompliant and Other Uncontacted Comparisons in the Matched Set	20	2	0	22
No Comparisons Contacted	29	4	0	33
Total	242	32	11	285

Originals. In two other cases, health records indicate that a health mismatch did in fact exist between the refusing Original and each uncontacted replacement Comparison in his matched set. In all of the remaining 48 matched sets, at least 1 uncontacted replacement Comparison matched the health status of the refusing Original Comparison and would have been eligible to participate in the study.

In conclusion, of 285 noncompliant Original Comparisons at the 1987 followup, all but 55 were members of matched sets having at least 1 other compliant replacement Comparison. Thirty-three of the 55 were noncompliant Original Comparisons whose replacements were never contacted, and 22 were members of matched sets in which all contacted replacements are noncompliant and at least 1 other replacement was uncontacted. Of these 55 noncompliant Original Comparisons, 48 belonged to matched sets containing at least 1 uncontacted replacement matched on health status to the refusing Original Comparison. Thus, 48 noncompliant Original Comparisons appeared not to have been replaced as required by the Protocol. The Air Force intended that additional replacements be contacted in a matched set until a health-matched compliant replacement is found. The effect of these oversights is considered negligible and these oversights will be corrected at the next examination.

PARTIALLY COMPLIANT VERSUS FULLY COMPLIANT PARTICIPANTS

In addition to the analyses summarized in Tables 5-8 and 5-9, a contrast of partially compliant versus fully compliant participants at the 1987 followup is presented. However, only 1 Ranch Hand and 27 Comparisons were partially compliant at the 1987 followup (Tables 5-1 and 5-2), precluding statistical analysis of these data for group differences. These individuals were administered the Baseline questionnaire in their homes but subsequently refused to attend the examination. The previous compliance of the 28 participants partially compliant at the 1987 followup is summarized in Table 5-12. Data on health status, medication use, and work loss of the 28 partially compliant and 2,294 fully compliant participants at 1987 followup are reported in Tables 5-13 through 5-15, respectively.

These data were sparse and were not considered supportive or nonsupportive of the compliance bias calculations presented in the Baseline report. The Baseline report conclusions regarding the potential effects of differential compliance should be regarded as conservative overestimates of bias but worthy of consideration until more data become available.

ANALYSIS OF PASSIVE REFUSALS

One of the reasons for refusal summarized in Table 5-16 was passive refusal. Passive refusal included failure to appear at a scheduled physical examination. There were 40 Ranch Hand, 53 Original Comparison, and 25 replacement Comparison passive refusals at the 1987 followup. Ranch Hand and Comparison passive refusals were contrasted with respect to reported health status. These data are summarized in Table 5-16.

TABLE 5-12.

**Previous Compliance Status of 28 Partially Compliant
Participants at the 1987 Followup**

Previous Compliance	Group		
	Ranch Hand	Original Comparison	Replacement Comparison
Refusal at Baseline and 1985 Followup	1	11	2
New to Study at 1985 Followup and Refusal at 1985 Followup	0	0	8
New to Study at 1987 Followup	0	0	6
Total	1	11	16

TABLE 5-13.

**Reported Health of Partially and Fully Compliant Participants
at the 1987 Followup**

1987 Followup Compliance	Reported Health	Group				Total
		Ranch Hand		Comparison		
		Number	Percent	Number	Percent	
Full	Excellent	474	47.6	651	50.2	1,125
	Good	454	45.6	560	43.1	1,014
	Fair	51	5.1	75	5.8	126
	Poor	16	1.6	12	0.9	28
Total		995		1,298*		2,293
Partial	Excellent	0	0.0	17	63.0	17
	Good	1	100.0	10	37.0	11
	Fair	0	0.0	0	0.0	0
	Poor	0	0.0	0	0.0	0
Total		1		27		28

*One participant answered "Don't know."

TABLE 5-14.

**Reported Medication Use of Partially and Fully Compliant Participants
at the 1987 Followup**

1987 Followup Compliance	Medication Use	Group				Total
		Ranch Hand		Comparison		
		Number	Percent	Number	Percent	
Full	Yes	253	25.4	332	25.6	585
	No	742	74.6	967	74.4	1,709
Total		995		1,299		2,294
Partial	Yes	0	0.0	2	7.4	2
	No	1	100.0	25	92.6	26
Total		1		27		28

TABLE 5-15.

**Reported Work Loss of Partially and Fully Compliant Participants
at the 1987 Followup**

1987 Followup Compliance	Work Loss	Group				Total
		Ranch Hand		Comparison		
		Number	Percent	Number	Percent	
Full	Yes	136	16.7	190	18.0	326
	No	675	83.2	867	82.0	1,542
Total		811		1,057		1,868*
Partial	Yes	0	0.0	2	7.7	2
	No	1	100.0	24	92.3	25
Total		1		26		27*

*One partially compliant and 426 fully compliant participants skipped this question.

TABLE 5-16.

Reported Health Status of Passive Refusals

Reported Health Status	Group						Total
	Ranch Hand		Original Comparison		Replacement Comparison		
	Number	Percent	Number	Percent	Number	Percent	
Excellent	16	40.0	28	52.8	15	60.0	59
Good	21	52.5	24	45.3	9	36.0	54
Fair	3	7.5	1	1.9	0	0.0	4
Poor	0	0.0	0	0.0	1	4.0	1
Total	40		53		25		118

The data indicated no significant association between group and reported health status among passive refusals ($p=0.170$). Additionally, health status was collapsed to excellent/good and fair/poor, and group was collapsed to Ranch Hand and Comparison because of sparse data in the full table. Analysis of the data from the collapsed table revealed no significant association between group and reported health status ($p=0.220$).

CONCLUSIONS

These compliance analysis results suggested that there has been no change in the way replacements self-selected for entry into this study from the Baseline and 1985 followup examinations. As stated in the two previous reports, there appears to be little selection bias due to nonparticipation.

Forty-eight of 285 noncompliant (refusing, partially compliant, or unlocatable) Original Comparisons were not replaced as required in the Protocol. The biasing effect of this omission is not known but is considered negligible.

CHAPTER 5

REFERENCES

1. Lathrop, G.D., S.G. Machado, T.G. Karrison, W.D. Grubbs, W.F. Thomas, W.H. Wolfe, J.E. Michalek, J.C. Miner, M.R. Peterson, and R.W. Ogershok. 1987. Epidemiologic investigation of health effects in Air Force personnel following exposure to herbicides: First followup examination results, NTIS: AD A 188 262. USAF School of Aerospace Medicine, Brooks Air Force Base, Texas.